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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,049	09/25/2000	Freda D. Miller	CIBT-P03-120	4083

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ROPES & GRAY
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/02/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/670,049

Applicant(s)

MILLER ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 21-34 and 36-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 35 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

Art Unit: 1646

DETAILED ACTION

Formal Matters

Claims 18-19 were amended, and new claims 43-46 were added, in Paper No. 13, 9/21/2002. Claims 1-46 are pending. Claims 1-17, 21-34, 36-42 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 18-20, 35, 43-46 are under consideration.

Response to Arguments and Amendment

Applicant's amendment, and arguments, filed 9/21/2002 have been fully considered but they are persuasive in part.

The rejection of claims 18-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn.

The rejection of claims 18-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ronnette et al. (U.S. Patent No. 5,318,907), has been withdrawn.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1646

Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed: the method of claim 18 or 19 wherein said epithelial tissue is not olfactory.

Applicant's amendment, Paper No. 13, 9/21/2002, does not provide sufficient direction for the written description for the above mentioned limitations of claim 45. The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide direction for the instant sequence encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1646

Claims 18-20 stand rejected, and claim 35 is rejected, under 35 U.S.C. 102(a) as being anticipated by Sosnowski et al. (1995), for reasons of record as set forth in Paper No. 13, 9/21/2002.

The rejection set forth that Sosnowski et al. (page 38, column 1, second paragraph to column 2, first paragraph) teaches a method of establishment in primary culture of olfactory epithelium isolated from adult mouse. Based upon immunoreactivity (page 45, column 1, fourth paragraph) to antibodies specific for intermediate filament proteins, the cells present in cultures were identified as neurons, glia or epithelial cells. Thus, the disclosure of Sosnowski meets the limitations of claims 18-20 and 35 of a method of producing a population of at least ten cells through the isolation of progenitor cells from peripheral tissue, in this instance olfactory epithelium, of a postnatal mammal. The cells isolated by Sosnowski et al. have been shown to be multipotent, due to the presence in culture of several cell types, thus meeting the limitation of claims 18-20 and 35.

Applicant argues that the teaching of Sosnowski et al. does not meet all of the limitations of the claims by not producing cells which are self-renewing and which differentiate in to ectodermal and mesodermal cell types. However, Sosnowski et al. teaches that the cultures established from regenerating olfactory tissue after chemical insult exhibited a range of neuronal yields (page 47, column 1, third paragraph). Cellular components of the cultures produced by Sosnowski et al. tested positive for keratin, as well as 200 kD and 160 kD neurofilament proteins, indicating the establishment of mixed olfactory epithelial cultures containing olfactory neurons (page 46, column 1, first paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-20, 35, 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sosnowski et al. (1995), in view of U.S. Patent no. 5,824,489 (Anderson et al.).

Sosnowski et al.(page 38, column 1, second paragraph to column 2, first paragraph) teaches a method of establishment in primary culture of olfactory epithelium isolated from adult mouse. Based upon immunoreactivity (page 45, column 1, fourth paragraph) to antibodies specific for intermediate filament proteins, the cells present in cultures were identified as neurons, glia or epithelial cells. Thus, Sosnowski teaches a method of producing a population of at least ten cells through the isolation of progenitor cells from peripheral tissue, in this instance olfactory epithelium, of a postnatal mammal. The cells isolated by Sosnowski et al. have been

Art Unit: 1646

shown to be multipotent, due to the presence in culture of several cell types. Sosnowski et al. teaches that the cultures established from regenerating olfactory tissue after chemical insult exhibited a range of neuronal yields (page 47, column 1, third paragraph). Cellular components of the cultures produced by Sosnowski et al. tested positive for keratin, as well as 200 kD and 160 kD neurofilament proteins, indicating the establishment of mixed olfactory epithelial cultures containing olfactory neurons (page 46, column 1, first paragraph).

Sosnowski et al. does not teach a method of producing a population of multipotent stem cells from epithelial tissue which is not olfactory, or which is skin or tongue. The '489 patent discloses multipotent neural stem cells can be derived from neural epithelial tissue from the brain and/or spinal cord of the adult central nervous system or neural epithelial tissue which may be present in tissues comprising the peripheral nervous system. In addition, the '489 patent discloses that such multipotent neural stem cells may be derived from other tissues such as lung, bone and the like (column 5, lines 40-47). Skin and tongue are tissues that comprise neurons of the peripheral nervous system. Therefore it would have been obvious to one of skill in the art at the time the invention was made to practice a method of producing a population of multipotent stem cells from epithelial tissue which is not olfactory, or which is skin or tongue. The motivation is provided in the '489 patent which discloses that the ability to isolate and grow mammalian neural crest stem cells in vitro allows for the possibility of using said stem cells to treat peripheral neurological disorders in mammals, particularly humans.

Conclusion

No claim is allowed.

Art Unit: 1646

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
November 21, 2002